

PATENT
Customer Number 22,852
Attorney Docket No. 08702.0081

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Man Sung Co, *et al.*) Group Art Unit: 1644
Serial No.: 09/249,011) Examiner: P. Gambel
Filed: February 12, 1999)
For: HUMANIZED IMMUNOGLOBULIN)
REACTIVE WITH B7-2 MOLECULES)
AND METHODS OF TREATMENT)
THEREWITH)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

MICROORGANISM DEPOSIT DECLARATION UNDER 37 C.F.R. § 1.808(a)

I, M. Andrea Ryan, do hereby declare and say that:

1. Genetics Institute, Inc. is the assignee of the above-identified patent application.
2. On information and belief, the recombinant CHO cell line which produces the humanized anti-B7-2 monoclonal antibody was deposited on May 5, 1998 under Accession Number CRL-12524 to assure availability of the cell culture to the public.
3. On information and belief, the A.T.C.C. has acquired the status of International Depository Authority within the meaning of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

RECEIVED
TPO/CP/10/2000
02 AUG 28 PM 3:25

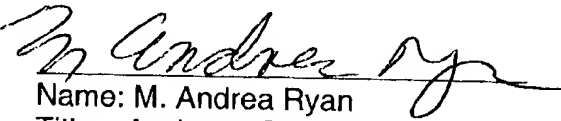
PATENT
Customer No. 22,852
Serial No. 09/249,011
Attorney Docket No. 08702.0081

4. Said culture has been deposited under conditions which ensure that access to the culture will be available during the pendency of this patent application to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under 37 C.F.R. Section 1.14 and 35 U.S.C. Section 1.22.

5. No later than issuance of a patent on this application, Genetics Institute will irrevocably remove any restrictions as to public availability of this culture deposit except as permitted by 37 C.F.R. Section 1.808(b), and will replace the culture deposit should it become nonviable, during the period that extends thirty years from the date of the deposit, or the period of the enforceable life of the patent, or the period of five years after the last public request for the deposit, whichever period is longest.

6. I further declare that all statements made herein of my own knowledge are true; that all statements made on information and belief are believed to be true; that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

8/28/02
Date


Name: M. Andrea Ryan
Title: Assistant Secretary

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Genetics Institute, Inc.
Attn: Gary Gray, Ph.D.
87 CambridgePark Drive
Cambridge, MA 02140

Deposited on Behalf of: Genetics Institute, Inc.

Identification Reference by Depositor:

ATCC Designation

Recombinant CHO GI-2G19-100

CRL-12524

The deposit was accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposit was received May 5, 1998 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested June 2, 1998. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara M. Hailey
Barbara M. Hailey, Administrator, Patent Depository

Date: June 24, 1998

cc: David E. Brook, Esq. (Ref. Docket GI-5815)

AMERICAN TYPE CULTURE COLLECTION
10801 University Boulevard
Manassas, VA 20110-2209 USA

Telephone: 703-365-2700

FACSIMILE

FAX

Date: June 2, 1998

To: David Brook
Hamilton, Brook et al

City & Country: Lexington, MA

Fax Number: 1-781-861-9540

Total number of pages including this page: One (1)

From: ATCC Patent Depository

ATCC Patent Depository Fax Number: 703-365-2745

Reference: Patent deposit, Dr. Gary Gray, Genetics Institute (Docket GI-5815).

CHO cell line GI-2G19-100 assigned ATCC CRL-12524. Date of deposit 5-05-98. Paperwork will be forwarded to you in a few days.

An invoice will be sent under separate cover as follows:

One time fee - 30 years
Informing of Requesters
Viability test

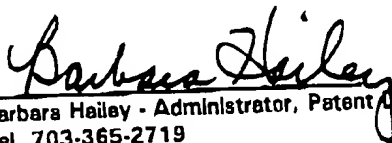
\$ 600.00
360.00
100.00

Total due ATCC CRL-12524
PAID BY CHECK 28792

\$1,060.00
-1,060.00

- 0 -

Balance due


Barbara Healey - Administrator, Patent Depository
Tel. 703-365-2719

The information contained in this facsimile is intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, you are notified that any dissemination or distribution, except to the intended recipient of this communication, is prohibited. If you have received this communication in error, please call us immediately at the telephone number listed above.

DAVID E. BROOK
JAMES M. SMITH
LEO M. REYNOLDS
PATRICIA GRANAHAN
JOHN L. DUPRE
DAVID J. BRODY
MARY LUC WAKIMURA
THOMAS O. HOOVER
ALICE O. CARROLL
N. SCOTT PIERCE
HELENE WENDLER
SUSAN G. L. GLOVSKY
DOREEN M. HOGUE
RICHARD W. WAGNER

GERALD M. BLUM
RAYMOND I. BRUTTOMESSO, JR.
BARRY W. CHAPIN
ANNE J. COLLINS
ROBERT T. CONWAY
STEVEN G. DAVIS
CAROL A. EGNER
ANTOINETTE G. GIUGLIANO
J. GRANT HOUSTON
DAVID E. HUANG
RODNEY D. JOHNSON
HELEN LEE
ELIZABETH W. MATA
TIMOTHY J. MEAGHER
NINA L. PEARLMUTTER
DEIRDRE E. SANDERS
ROBERT J. SAYRE
LISA M. TREANNIE
DARRELL L. WONG
* NOT ADMITTED IN MASS

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

TWO MILITIA DRIVE - LEXINGTON, MASSACHUSETTS 02173-4799
TELEPHONE: (781) 861-6240 - FACSIMILE: (781) 861-9540
PATENTS, TRADEMARKS, COPYRIGHTS AND LITIGATION

FILE COPY

MUNROE H. HAMILTON
(1906-1984)

CAROLIN S. ELMORE
SUPERVISING PATENT AGENT

OF COUNSEL

RICHARD A. WISE
DAVID J. THIBODEAU, JR.

TECHNICAL SPECIALISTS

SUSAN M. ABELLEIRA
SANDRA A. BROCKMAN
THERESA A. DEVLIN
STEPHEN J. GAUDET
EDGAR W. HARLAN
JOYCE C. MILLER
MARY F. MURRAY
KENYON L. SCHUETT

JOHN W. MEDBURY
ADMINISTRATIVE DIRECTOR

BARBARA J. FORGUE
ADMINISTRATOR OF PATENT
AND TRADEMARK PRACTICE

April 30, 1998

VIA FEDERAL EXPRESS

Ms. Barbara Hailey
Administrator
Patent Depository
American Type Culture Collection
12301 Parklawn Drive
Rockville, Maryland 20852

Re: Check in Payment for Deposit by Dr. Gary Gray on behalf of
Genetics Institute
GI-5815, "Humanized Immunoglobulin for B7.2"

Dear Ms. Hailey:

Enclosed please find a check in the amount of \$1060, which includes the fee for storage and maintenance under the Budapest Treaty (\$600), fee for viability testing (\$100) and fee for 30-year notification of requestors (\$360). This check is in payment for a deposit which is being forwarded to you by:

Dr. Gary S. Gray
Senior Scientist
Genetics Institute
87 Cambridge Park Drive
Cambridge, MA 02140

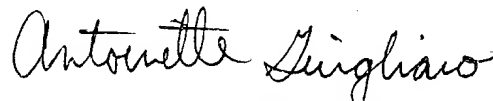
Also enclosed please find a copy of the BP/1 form signed by Dr. Gray. Dr. Gray will forward the deposit with a signed and completed deposit form (BP/1) to the ATCC under separate cover. The deposit is being made in connection with a new U.S. Patent Application (corresponding to our Attorney Docket No. GI-5815).

Ms. Barbara Hailey
April 30, 1998
Page 2

The ATCC is authorized to charge any additional fees relating to this matter to our account (No. 4762).

Please forward the notification to David E. Brook at (781) 861-9540. Thank you for your help in this matter.

Very truly yours,



Antoinette G. Giugliano

AGG/jw
Enclosure

cc: Scott A. Brown, Esq.
Gary S. Gray, Ph.D.
Ms. Trudy Veldman
Ms. Judy Barrett
David E. Brook, Esq.
Anne J. Collins, Esq.

K:\AGIUGLIA\GI\5815\CORRES\ATCC.LTR

Budapest Treaty Deposits

American Type Culture Collection

12301 Parklawn Drive, Rockville, MD 20852 USA, Telephone (301) 231-5519/5620 Fax (301) 816-4366

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

All questions must be completed.

1. Name of deposit. (If microorganism, complete scientific name including genus and species and source of material; If virus, name and whether or not plant or animal and source including geographic location; if cell line, provide tissue & species, geographical source of isolation and any known hazards associated (e.g. HIV, EBV, etc.); if genetic materials, name of organism from which vector, clone or library is derived, source of the DNA insert identified by species (e.g. human, mouse) or scientific name and provide name of gene and identity of the host organism.)
Recombinant CHO (Chinese hamster ovary; #PA-CHO-DOKX-153.8) cell line
expressing genes for the humanized anti-human B7.2 (CD86) monoclonal
antibody (#HF2.3D1).
2. Strain designation (i.e., number, symbols, etc.) GI-2G19-100
3. Is this an original deposit under the Budapest Treaty? Yes
4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty? If so, please indicate ATCC designation. No
5. Is this deposit a mixture of microorganisms or cells? No
6. Provide details necessary to cultivate test for viability and store deposit. If mixture, provide description of components and a method to check presence. (If plasmid, provide name of host & antibiotic resistance). Culture cells in alpha-MEM
medium containing 2 mM glutamine, 10% fetal calf serum, & 0.1 uM methotrexate.
Culture cells at 37°C, 7.5% CO₂. Store cells in suitable mammalian cell line
storage medium in liquid nitrogen.
7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod). CHO cells line
expressing a human anti-human B7.2 (CD86) monoclonal antibody of IgG2 isotype.
 - a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list the antibiotics Culture in
0.1uM methotrexate.
 - b. If deposit is a hybridoma, what is the isotype of antibody produced? _____
8. Is this strain hazardous to humans? No, animals? No, plants? No. If yes, what is the recommended biosafety level for working with this strain BL-1 (Ref. Guidelines for Research Involving Recombinant DNA Molecules, NIH Guidelines, January 1996) (www.nih.gov/od/orda/toc.htm)
9. Availability: Prior to issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent patent office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered
 - a. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit made available to anyone who requests a culture? If yes, there are no restrictions on distribution. Yes _____ No No
 - b. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit made available to requesters which satisfy Patent Offices in countries not signatory to the Budapest Treaty? If "yes," please state which countries below. Yes _____ No No

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty, and your deposit has already been released for distribution due to the issuance of a U.S. Patent, you cannot restrict it from further distribution.

After a U.S. Patent issues, and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under U.S. Patent and Trademark Office Rules and Regulations (37 CFR § 1.808 [a](2)).

10. Do you wish ATCC to inform you of all requests for this strain? Yes x No

11. ATCC will notify you of your ATCC after confirmation of viability testing is complete. (No Charge).

Name of Individual to notify: David E. Brook, Esq.

Fax No. (781) 861-9540

Telephone No. (781) 861-6240

12. Payment by check, or credit card (MasterCard, VISA or American Express), must accompany the deposit unless prior arrangements for billing have been made and approved. If arrangements have been made to bill you for services, please indicate person who should receive invoice. Also, please include P.O. number.

A check for \$1060 (\$600 for 30 years storage; \$100 for viability testing; \$360 for 30-year notification of requests) is being sent from Hamilton,

Credit Card number (indicate MasterCard, VISA, Brook, Smith & Reynolds, P.C. with authorization or American Express) Expiration Date to charge additional fees to

Account No. 4762.

Type or print the name shown on credit card

Signature

For ATCC use only: Auth:

ROC #:

13. Name, address, telephone and facsimile number of your attorney of record. David E. Brook, Esq.
Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Dr., Lexington, MA 02173
tel (781) 861-6240/fax (781) 861-9540 (Ref: Docket or Case No. GI-5815)

14. MUST BE COMPLETED. Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institute, and normally is not an individual.) Genetic Institute, 87 Cambridge Park Drive, Cambridge, MA 02140. Deposit is made on behalf of Genetics Institute
in connection with a new application corresponding to our docket no. GI-5815.

I understand and agree that the deposit may not be withdrawn by me for a period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Gary Gray, Ph.D.

✓ Typed Name

Gary Gray
Signature

April 29, 1998
Date

Address. 87 Cambridge Park Drive
Cambridge, MA 02140

THIS FORM MUST BE COMPLETED IN ENGLISH

ADDRESS SHIPMENTS AND FORM TO THE ATTENTION OF:

Patent Depository
American Type Culture Collection
12301 Parklawn Drive
Rockville, MD 20852 U.S.A.

ALL FEES SUBJECT TO CHANGE:

FEES: 30 years' storage \$800. 30 years' notification \$360. Viability testing \$100 to \$400 or quoted price, dependent upon necessary material and/or equipment. Prepare additional samples of cells or hybridomas \$500. Return sample for approval (if not submitted frozen or freeze-dried or the required number) \$130. Additional costs for return of samples outside U.S.A. STORAGE: Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

ATCC USE ONLY: ATCC DESIGNATION REC'D V.T. RESULT

Name of Deposit Strain Designation

Form 88/1 Page 2 of 2 Rev. 1/97

Budapest Treaty Deposits

American Type Culture Collection

12301 Parklawn Drive, Rockville, MD 20852 USA, Telephone (301) 231-5519/5620 Fax (301) 816-4366

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

All questions must be completed.

1. Name of deposit. (If microorganism, complete scientific name including genus and species and source of material; If virus, name and whether or not plant or animal and source including geographic location; if cell line, provide tissue & species, geographical source of isolation and any known hazards associated (e.g. HIV, EBV, etc.); if genetic materials, name of organism from which vector, clone or library is derived, source of the DNA insert identified by species (e.g. human, mouse) or scientific name and provide name of gene and identity of the host organism.)
Recombinant CHO (Chinese hamster ovary; #PA-CHO-DUKX-153.8) cell line
expressing genes for the humanized anti-human B7.2 (CD86) monoclonal
antibody (#HF2.3D1).
2. Strain designation (i.e., number, symbols, etc.) GI-2G19-100
3. Is this an original deposit under the Budapest Treaty? Yes
4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty? If so, please indicate ATCC designation. No
5. Is this deposit a mixture of microorganisms or cells? No
6. Provide details necessary to cultivate test for viability and store deposit. If mixture, provide description of components and a method to check presence. (If plasmid, provide name of host & antibiotic resistance). Culture cells in alpha-MEM
medium containing 2 mM glutamine, 10% fetal calf serum, & 0.1 uM methotrexate.
Culture cells at 37°C, 7.5% CO₂. Store cells in suitable mammalian cell line
storage medium in liquid nitrogen.
7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod). CHO cells line
expressing a human anti-human B7.2 (CD86) monoclonal antibody of IgG2 isotype.
 - a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list the antibiotics Culture in
0.1uM methotrexate.
 - b. If deposit is a hybridoma, what is the isotype of antibody produced? _____
8. Is this strain hazardous to humans? No, animals? No, plants? No. If yes, what is the recommended biosafety level for working with this strain BL-1. (Ref. Guidelines for Research Involving Recombinant DNA Molecules, NIH Guidelines, January 1996) [www.nih.gov/od/orda/toc.htm]
9. **Availability:** Prior to issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples **must be** provided to a specific investigator if a pertinent patent office under the Budapest Treaty instructs ATCC to do so. The following questions **must be answered**.
 - a. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit made available to anyone who requests a culture? If yes, there are no restrictions on distribution. Yes _____ No No
 - b. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit made available to requesters which satisfy Patent Offices in countries not signatory to the Budapest Treaty?
If "yes," please state which countries below. Yes _____ No No

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty, and your deposit has already been released for distribution due to the issuance of a U.S. Patent, you cannot restrict it from further distribution.

After a U.S. Patent issues, and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under U.S. Patent and Trademark Office Rules and Regulations (37 CFR § 1.808 [a][2]).

10. Do you wish ATCC to inform you of all requests for this strain? Yes x

11. ATCC will notify you of your ATCC number after confirmation of viability testing is complete (No Charge).
Name of Individual to notify: David E. Brook, Esq.

Fax No. (781) 861-9540

Telephone No. (781) 861-6240

12. Payment by check, or credit card (MasterCard, VISA or American Express), must accompany the deposit unless prior arrangements for billing have been made and approved. If arrangements have been made to bill you for services, please indicate person who should receive invoice. Also, please include P.O. number.

A check for \$1060 (\$600 for 30 years storage; \$100 for viability testing; \$360 for 30-year notification of requests) is being sent from Hamilton,

Credit Card number (indicate MasterCard, VISA, Brook, Smith & Reynolds, P.C. with authorization or American Express) _____

Expiration Date to charge additional fees to
Account No. 4762.

Type or print the name shown on credit card _____

Signature _____

For ATCC use only: Auth: _____

ROC #: _____

13. Name, address, telephone and facsimile number of your attorney of record. David E. Brook, Esq.
Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Dr., Lexington, MA 02173
tel (781) 861-6240/fax (781) 861-9540 (Ref: Docket or Case No. GI-5815)

14. **MUST BE COMPLETED.** Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institute, and normally is not an individual.) Genetic Institute, 87 Cambridge Park Drive, Cambridge, MA 02140. Deposit is made on behalf of Genetics Institute
in connection with a new application corresponding to our docket no. GI-5815.

I understand and agree that the deposit may not be withdrawn by me for a period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

✓ Gary Gray, Ph.D.

Typed Name

Gary Gray
Signature

April 29, 1998
Date

Address: 87 Cambridge Park Drive
Cambridge, MA 02140

THIS FORM MUST BE COMPLETED IN ENGLISH

ADDRESS SHIPMENTS AND FORM TO THE ATTENTION OF:

Patent Depository
American Type Culture Collection
12301 Parklawn Drive
Rockville, MD 20852 U.S.A.

ALL FEES SUBJECT TO CHANGE:

FEES: 30 years' storage \$600 30 years' notification \$360. Viability testing \$100 to \$400 or quoted price, dependent upon necessary material and/or equipment. Prepare additional samples of cells or hybridomas \$500. Return sample for approval (if not submitted frozen or freeze-dried or the required number) \$130. Additional costs for return of samples outside U.S.A. **STORAGE:** Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

ATCC USE ONLY: ATCC DESIGNATION _____ REC'D _____ V.T. RESULT _____

Name of Deposit _____ Strain Designation _____

Form BP/1 Page 2 of 2 Rev. 1/97

Alan Harris Ph.D.
Project Director

GENETICS  INSTITUTE

A Subsidiary of American Home Products Corporation

GENETICS  INSTITUTE

87 CambridgePark Drive
Cambridge, MA 02140
Telephone (617) 503-7425
Telefax (617) 498-8863
aharris@genetics.com

F A X

FAX

TO: Antoinette Giugliano HAMILTON, BROOK, SMITH, REYNOLDS

781 - ~~861~~ - 9540

861

FROM: Gary Gray/Genetics Institute

DATE: 29 April 1998

Number of pages including title page: 3

MESSAGE:

enclosed please find a FAX from Gary Gray

Budapest Treaty Deposits

American Type Culture Collection

12301 Parklawn Drive, Rockville, MD 20852 USA. Telephone (301) 231-5519/5620 Fax (301) 816-4366

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF BUDAPEST
TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

All questions must be completed.

1. Name of deposit. (If microorganism, complete scientific name including genus and species and source of material: If virus, name and whether or not plant or animal and source including geographic location; if cell line, provide tissue & species, geographical source of isolation and any known hazards associated (e.g. HIV, EBV, etc.); if genetic materials, name of organism from which vector, clone or library is derived, source of the DNA insert identified by species (e.g. human, mouse) or scientific name and provide name of gene and identity of the host organism.)
1A-CHO-DOCK # 1538
Recombinant CHO cell line expressing genes for a
humanized anti human B7.2 monoclonal antibody (# HP2.3D)
(C086)
2. Strain designation (i.e., number, symbols, etc.) GI-2919-100
3. Is this an original deposit under the Budapest Treaty? YES
4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty? If so, please indicate ATCC designation. NO
5. Is this deposit a mixture of microorganisms or cells? NO
6. Provide details necessary to cultivate test for viability and store deposit. If mixture, provide description of components and a method to check presence. (If plasmid, provide name of host & antibiotic resistance). culture in
alpha-MEM, 2 mM glutamine, 10% FBS, 0.1 μm methotrexate
7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod). CHO cell
gene expressing human anti human B7.2 mAb IgG2 subtype
(C086)
- a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list the antibiotics 0.1 μm methotrexate
- b. If deposit is a hybridoma, what is the isotype of antibody produced? _____
8. Is this strain hazardous to humans? _____ animals? _____, plants? _____. If yes, what is the recommended biosafety level for working with this strain _____. (Ref. Guidelines for Research Involving Recombinant DNA Molecules, NIH Guidelines, January 1996) [www.nih.gov/od/orda/toc.htm]
9. Availability: Prior to issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent patent office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered.
- a. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit made available to anyone who requests a culture? If yes, there are no restrictions on distribution. Yes _____ No *
- b. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit made available to requesters which satisfy Patent Offices in countries not signatory to the Budapest Treaty? If "yes," please state which countries below. Yes _____ No *

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty, and your deposit has already been released for distribution due to the issuance of a U.S. Patent, you cannot restrict it from further distribution.

After a U.S. Patent issues, and we are so notified, ATCC makes the culture available to anyone who requests it, as allowed under U.S. Patent and Trademark Office Rules and Regulations (37 CFR § 1.808 [a][2]).

10. Do you wish ATCC to inform you of all requests for this strain? Yes * No _____
11. ATCC will notify you of your ATCC number after confirmation of viability testing is complete (No Charge).
Name of Individual to notify: DAVID E BROOK ESQ
Fax No. (781)-861-9540 Telephone No. 781-861-6240
12. Payment by check, or credit card (MasterCard, VISA or American Express), must accompany the deposit unless prior arrangements for billing have been made and approved. If arrangements have been made to bill you for services, please indicate person who should receive invoice. Also, please include P.O. number.

Card number (indicate MasterCard, VISA, or American Express)
No. _____ Expiration Date _____
Type or print the name shown on credit card _____ Signature _____
- For ATCC use only: Auth: _____ ROC #: _____
13. Name, address, telephone and facsimile number of your attorney of record. _____

(Ref: Docket or Case No. _____)
14. **MUST BE COMPLETED.** Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institute, and normally is not an individual.) _____

I understand and agree that the deposit may not be withdrawn by me for a period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Typed Name _____ Signature _____ Date _____
Address _____

THIS FORM MUST BE COMPLETED IN ENGLISH

ADDRESS SHIPMENTS AND FORM TO THE ATTENTION OF:

Patent Depository
American Type Culture Collection
12301 Parklawn Drive
Rockville, MD 20852 USA

ALL FEES SUBJECT TO CHANGE:

FEES: 30 years' storage \$600. 30 years' notification \$360. Viability testing \$100 to \$400 or quoted price, dependent upon necessary material and/or equipment. Prepare additional samples of cells or hybridomas \$500. Return sample for approval (if not submitted frozen or freeze-dried or the required number) \$130. Additional costs for return of samples outside USA. **STORAGE:** Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

ATCC USE ONLY: ATCC DESIGNATION _____ REC'D _____ V.T. RESULT _____
Name of Deposit _____ Strain Designation _____

SENT BY: GENETICS INSTITUTE
Feb-12-99 14:17 From: HBSR

99 : 3:57PM :

LEGAL DEP
17818618540

17818618540:# 1/ 2
T-520 P 01/02 F-828

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
Two Milina Drive
Lexington, MA 02421-4702

FAX

Telephone: (781) 861-6240

Facsimile: (781) 861-9540

FACSIMILE COVER SHEET

Date:

February 12, 1999

To:

Scott A. Brown, Esq.

Client Code:

1290

Fax Number:

(617) 876-5851

From:

Antoinette G. Giugliano, Esq. *AGG*

Subject:

GI-5315

Number of pages including this cover sheet: 2

Please confirm receipt of facsimile: Yes ☒ No ☐

Comments:

To: A. Giugliano

Privileged and Confidential - All information transmitted hereby is intended only for the use of the addressee(s) named above. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient(s), please note that any distribution or copying of this communication is strictly prohibited. Anyone who received this communication in error is asked to notify us immediately by telephone and to destroy the original message or return it to us at the above address via first class mail.

AUTHORISATION UNDER RULE 28(1)(d) EPC

DEPOSIT OF BIOLOGICAL MATERIAL

Representatives' Reference GI-5315

I (We)¹:

Genetics Institute, Inc
87 Cambridge Park Drive
Cambridge, MA 02140, USA

have deposited with²: American Type Culture Collection
under accession No. CRL-12524 biological material in accordance with the Budapest
Treaty (or, where applicable, the bilateral agreement between the EPO and the depositary
institution concerned).

I (We) hereby authorise³

Gary S. Gray, Abigail Celniker, Bonita Rup, Denise O'Hara, Samuel Goldman,
Andrea Knight, Trudi Veldman, Beatriz Carreno, Mary Collin, Man Sung Co and
Maximiliano Vasquez

to refer to the aforementioned deposited biological material in European (or International) patent
application No.⁴ GI-5815 and give my (our) unreserved and irrevocable consent to the
deposited material being made available to the public in accordance with Rule 28 EPC.

Place

CAMBRIDGE, MA

Date

2/2/99

Signature(s)⁵:

B. Leicher

Bruce Leicher
Vice President - Law
for Genetics Institute, Inc.

- 1 Insert in full, name and address of depositor, for individuals surname should be given first
- 2 Insert name of recognised depositary institution.
- 3 Insert name of applicant for patent
- 4 Where number not available insert applicant's/representative's reference number
- 5 Capacity of signatory should be stated

AUTHORISATION UNDER RULE 28(1)(d) EPC

DEPOSIT OF BIOLOGICAL MATERIAL

Representatives' Reference GI-5315

I (We)¹:

Genetics Institute, Inc.

87 Cambridge Park Drive

Cambridge, MA 02140, USA

have deposited with²: American Type Culture Collection
under accession No. CRL-12524 biological material in accordance with the Budapest
Treaty (or, where applicable, the bilateral agreement between the EPO and the depositary
institution concerned).

I (We) hereby authorise³:

Gary S. Gray, Abigail Celniker, Bonita Rup, Denise O'Hara, Samuel Goldman,

Andrea Knight Trudi Veldman, Beatriz Carreno, Mary Collin, Man Sung Co and

Maximiliano Vasquez

to refer to the aforementioned deposited biological material in European (or International) patent
application No.⁴ GI-5815 and give my (our) unreserved and irrevocable consent to the
deposited material being made available to the public in accordance with Rule 28 EPC.

Place _____

Date _____

Signature(s)⁵: _____

Bruce Leicher

Vice President - Law

for Genetics Institute, Inc.

-
1. Insert in full: name and address of depositor, for individuals surname should be given first.
 2. Insert name of recognised depositary institution.
 3. Insert name of applicant for patent.
 4. Where number not available insert applicant's/representative's reference number.
 5. Capacity of signatory should be stated.